REMARKS

Claims 54, 57-59, 61-69, and 88-98 are now pending in the application, claims 99-124 having been canceled by the present amendment (and claims 1-53, 55-56, 60, and 70-87 having been previously canceled (see the section below regarding the claim numbers). Claims 54, 57 and 61 have been amended. No new matter has been added.

Clarification of Claim Numbering

In the present Office action, claims 53, 56-58, 60-68, and 87-123 are listed as the claims pending (see the Office Action Summary). Applicants believe these claim numbers are incorrect; the claims pending at the time the Office Action was issued were, instead, claims 54, 57-59, 61-69, and 88-124. This inconsistency may have arisen because the Examiner did not realize that the application was filed with two different claims being numbered as claim 48; upon discovery of that error, the second claim 48 was renumbered claim 49 and original claims 48-52 were renumbered as claims 48-53 (by the Office action mailed October 14, 1999 (paper number 15)). Thus, it was proper for the next added claim to be numbered claim 54 (not 53, as one might expect given the number (52) of the last original claim). Applicants respectfully request confirmation that the claims pending and examined in the prior Office action were claims 54, 57-59, 61-69, and 88-124.

In the remarks that follow, Applicants use the Examiner's recent claim numbers followed, in parentheses, by the claim numbers they believe to be correct.

35 U.S.C. § 102

Claims 53, 56, 60-68 and 87-95 (*i.e.*, claims 54, 57, 61-69 and 88-96) were rejected for lack of novelty in view of U.S. Patent No. 6,338,952 (herein, "Young"). The Examiner states that Young discloses a stress protein fused to an antigen and that the antigen can be a bacterial, viral, parasitic, or other antigen (Office action at page 3, citing Young at column 11, lines 58-63 and column 9, lines 62-67). The Examiner contends that this disclosure "would meet all of the limitations included in claim 53 (*i.e.*, claim 54)" (Office action at page 3). Claim 56 (*i.e.*, claim 57) further limited claim 53 (*i.e.*, claim 54) by specifying that the antigen of the influenza

virus is hemagglutinin, nucleoprotein, neuraminidase, M1, M2, PB1, PB2, or PA. The Examiner states that claim 56 (*i.e.*, claim 57) is anticipated by Young's disclosure at column 12, lines 8-24.

In view of the present amendment of claims 53 and 56 (*i.e.*, claims 54 and 57), this ground for rejection should be withdrawn.

As the Examiner knows, the test for anticipation is only satisfied when a composition (or process) in the prior art is identical to the composition (or process) claimed. Anticipation under 35 U.S.C. § 102 can be found only if a reference shows exactly what is claimed. *See, e.g., Titanium Metals Corp. v. Banner* 778 F.2d 775 (Fed. Cir. 1985). *See also, Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299 (Fed. Cir. 1995). ("Invalidity based on lack of novelty (often called 'anticipation') requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee.")

Claim 53 (*i.e.*, claim 54), as before, covers a "fusion protein comprising an antigen of an influenza virus, or an antigenic portion thereof, and a stress protein, or a portion thereof," and, with the present amendment, the "wherein" clause includes the phrase, "wherein the antigen is nucleoprotein, neuraminidase, M1, M2, PB1, PB2 or PA." Claim 61 (*i.e.*, claim 62) has been similarly amended. Claim 56 (*i.e.*, claim 57) has been amended so that the only recited antigen is nucleoprotein.

Young does not disclose any of the influenza antigens now recited in amended claims 53 and 60 (*i.e.*, claims 54 and 61); Young does not disclose nucleoprotein, neuraminidase, M1, M2, PB1, PB2, or PA. As Young does not disclose exactly what is now claimed, Young cannot anticipate the compositions now claimed. Moreover, while the prior disclosure of a species within a genus defeats a claim to that genus, the disclosure of a genus does not necessarily render non-disclosed species within it unpatentable. *See Chester v. Miller*, 906 F.2d 1574 (Fed. Cir. 1990). As all of the remaining pending claims depend, or ultimately depend, from either claim 53 or claim 60 (*i.e.*, claim 54 or claim 61), Young cannot anticipate the subject matter of those claims. Accordingly, this ground for rejection cannot stand.

35 U.S.C. § 103

Claims 57 and 58 (*i.e.*, 58 and 59) were rejected as being obvious over Young (Office action at page 6). The Examiner's reasoning is reproduced here for the sake of completeness and easy reference (Office action at page 6):

> Young teaches the subcloning of the HIV p24 gag gene into the stress protein fusion vector pKS70 to produce the pKS72 vector (column 12, lines 40-47) and further states that a stress protein could be conjugated to ANY antigen, thus meeting the limitations of claims 57 and 58. While the plasmid vectors are not the same, it would have been prima facie obvious to one of ordinary skill in the art to have modified the methods of Young, using a favorable or comparable plasmid vector suitable to facilitate the particular antigen of interest and this could be done with a reasonable expectation of success.

This ground for rejection is respectfully traversed. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP at 2143.

As the Examiner notes, claim 57 (*i.e.*, claim 58) covers the fusion protein of claim 54 when that fusion is encoded by plasmid pET65MP/NP-B or plasmid pET65MP/NP-D. Young cannot render the fusion protein claimed in claim 57 (*i.e.*, claim 58) obvious because Young does not disclose the influenza antigens of claim 54 (which are incorporated by reference in dependent claim 57 (*i.e.*, claim 58)), let alone the plasmids specifically recited in claim 57 (*i.e.*, claim 58). Similarly, claim 58 (*i.e.*, claim 59) depends from claim 54 and, therefore, also covers fusion proteins having the specific influenza antigens recited in claim 54. Young does not disclose these antigens. Young must teach or suggest all the claim limitations, and it fails to do so. On this ground alone, the rejection for obviousness must be withdrawn.

Claims 98-123 (*i.e.*, claims 99-124) were rejected as being unpatentable over Young in view of Srivastava (U.S. Patent No. 6,030,618) (Office action at page 6). Claims 98-123 (*i.e.*, claims 99-124) have been canceled. This ground for rejection is now moot.

Claims 89-123 (*i.e.*, claims 99-124) were rejected as being unpatentable over Young and in further view of Lathe *et al.* (U.S. Patent No. 6,007,806) "for the reasons set forth in the previous office action" (Office action at page 7).

Claims 99-124 (which the Examiner would have referred to as claims 98-123) been canceled. Thus, the rejection is moot with respect to those claims. With respect to claims 89-98 (really, claims 90-99), this ground for rejection should be withdrawn. The Lathe patent is wholly limited to antigens of human papillomavirus. Indeed, in the last Office action (to which the Examiner refers), Lathe was characterized as follows (Office action mailed August 28, 2001 (paper number 31) at page 4):

> Lathe et al. (US 5,858,368) discloses recombinant fusion proteins wherein HPV antigens are recombinantly produced for use in a vaccine against HPV-induced tumors. The preferred HPV antigens include E6 and E7 (columns 16-18). Lathe et al. disclose that the HPV E6 and E7 proteins are useful for induction of an immune response to the HPV antigen. Further, the recombinant proteins are easier to produce in large quantities in comparison to purification from viral culture. These proteins (in pharmaceutical compositions) are immunogenic, and used by Lathe to treat and/or prevent tumors of HPV origin. This regression and/or prevention of HPV tumors shows that the E6 and the E7 are each able to activate immune effector cells necessary for the elimination and/or prevention of the tumor cells.

As noted above, the present claims cover fusion proteins containing particular influenza antigens. Nothing in Lathe suggests these antigens and Young, alone, cannot render them obvious for the reasons given above. The Examiner is respectfully asked to reconsider and withdraw this ground for rejection.